

(b) detecting the hybridization complex, wherein the presence of the hybridization complex correlates with the presence of the target polynucleotide in the sample.

28. (Reiterated) The method of claim 27 further comprising amplifying the target polynucleotide prior to hybridization.

Please add the following claim.

29. (New) A method for detecting a target polynucleotide in a sample, said target polynucleotide comprising a polynucleotide sequence selected from the group consisting of a polynucleotide sequence of SEQ ID NO:1, a naturally occurring polynucleotide sequence having at least 90% sequence identity to a polynucleotide sequence of SEQ ID NO:1, a polynucleotide sequence complementary to a polynucleotide sequence of SEQ ID NO:1, and a polynucleotide sequence complementary to a naturally occurring polynucleotide sequence having at least 90% sequence identity to a polynucleotide sequence of SEQ ID NO:1, the method comprising:

- c3
- a) amplifying said target polynucleotide or fragment thereof using polymerase chain reaction amplification, and
 - b) detecting the presence or absence of said amplified target polynucleotide or fragment thereof, and, optionally, if present, the amount thereof

REMARKS

1. Restriction Requirement

Claims 4-7 and 14-28 are pending in the application and were subject to a Restriction Requirement. The Examiner stated that "During a telephone conversation with Susan Sather on 8/15/00 a provisional election was made with traverse to prosecute the invention of group I, claims 2-4, 6, 7, 19-20 and 22. Affirmation of this election must be made by applicant in replying to this Office Action." (Office Action, page 3, Item 4). Applicant note that the claims of Group I as listed by the Examiner in this statement are not correct. Group I should contain

Claims 4, 6, 7, 19, 20, 23, 24, 25, 27, and 28. Applicants and the Examiner have had several communications concerning the claims of Group I which are summarized below.

May 3, 2000	Examiner sent a written Restriction Requirement. Group I was listed as containing Claims 2-4, 6, 7, and 19-22. Pending claims were listed as Claims 2-7 and 12-28 on the Office Action Summary, but in the Detailed Action, page 2, the pending claims listed in the Groups were 2-7, 11-22, and 26.
May 30, 2000	Applicants' Agent informed Examiner in a telephone conversation that the pending claims listed in the written Restriction Requirement were incorrect. Claims 2, 3, and 11-13 had been canceled, and Claims 23, 24, 25, 27, and 28 had been added in the Preliminary Amendment filed December 10, 1999.
May 31, 2000	Applicants' Agent and Examiner agreed in a telephone conversation that the pending claims were 4-7 and 14-28 and to reformulate the Restriction Requirement such that Group I contained Claims 4, 6, 7, 19-25, 27, and 28.
June 5, 2000	Applicants filed a Response to Restriction Requirement summarizing the telephone conversation of May 31, 2000 and elected Group I, which included Claims 4, 6, 7, 19-25, 27, and 28.
August 16, 2000	Examiner telephoned Applicants' Agent and informed her that Claim 21 should not be in Group I, but should be in its own group. Applicants' Agent agreed to elect the reformulated Group I, now containing 4, 6, 7, 19-25, 27, and 28.

Therefore, Applicants affirm election, with traverse, to prosecute Group I, which includes

and is drawn to Claims 4, 6, 7, 19, 20, 22-25, 27, and 28. Applicants submit that the invention encompassed by the claims of Group I (drawn to polynucleotides, compositions, cells and organisms transformed with said polynucleotide, methods of producing a polypeptide, and methods of detecting said polynucleotides) could be examined at the same time as the invention encompassed by the claim of Group VII (Claim 26). For example, a search of the prior art to determine the novelty of the method for detecting a target polynucleotide in a sample would also provide information regarding the novelty of the method for screening a compound for effectiveness in altering expression of a target polynucleotide. See also the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Accordingly, because the searches required to identify prior art relevant to the claims of Groups I and VII would substantially overlap, Applicants respectfully submit that examination of originally filed claims 4, 6, 7, 19-22, 23, 24, 25, 26, 27, and 28 would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of the claims in Groups I and VII. Applicants reserve the right to prosecute the non-elected claims in subsequent divisional applications.

2. Objection to Claims 4, 6, and 7

The Examiner objected to Claims 4, 6, and 7 for depending from canceled Claims 2 and 3. Applicants have canceled Claims 4, 6, and 7 and therefore the objection is moot. The subject matter of Claims 6 and 7 is encompassed with greater clarity and more specificity in the method of detection claims of Claims 23, 24, 25, and 27-29. Therefore, Applicants respectfully request that the Examiner withdraw the objections to Claims 4, 6, and 7.

3. Rejection of Claims 19, 20, and 22 Under 35 U.S.C. § 112, second paragraph

The Examiner rejected Claims 19, 20 and 22 under 35 U.S.C. § 112, second paragraph, in particular for reciting the phrase "biologically active."

Applicants submit that Claims 19, 20, and 22 as originally written were clear and definite.

However, in order to expedite prosecution, Applicants have amended Claims 19 and 22 to recite a "fragment of an amino acid sequence of SEQ ID NO:2, wherein said fragment has kinase activity." Kinase activity is described in the Specification e.g., on page 26, line 17 through page 27, line 18. Kinase activity assays are also well-known in the art.

Therefore amended Claims 19 and 22, as well as Claim 20 which depends from Claim 19, are clear and definite. Applicants respectfully request that the Examiner withdraw the rejection of Claims 19, 20, and 22 under 35 U.S.C. § 112, second paragraph.

4. Rejection of Claim 4 Under 35 U.S.C. § 112, first paragraph, written description

The Examiner rejected Claim 4 under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." (Office Action, page 5.)

Applicants have canceled Claim 4 and therefore the rejection is moot. Applicants respectfully request that the Examiner withdraw the rejection of Claim 4 under 35 U.S.C. § 112, first paragraph on this basis.

5. Rejection of Claims 19, 20, and 22 Under 35 U.S.C. § 112 first paragraph, enablement

The Examiner rejected Claims 19, 20, and 22 under 35 U.S.C. § 112 first paragraph, stating that "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the invention commensurate in scope with these claims." (Office Action, page 6.) The Examiner stated that the specification was enabling "for a recombinant polynucleotide comprising a promoter sequence operably linked to a polynucleotide encoding a polypeptide having at least 90% sequence identity to the amino acid sequence of SEQ ID NO:2, wherein said polypeptide has kinase activity. . ." (Office Action, page 6.)

The Examiner made the rejection in two parts, focusing on the "how to use" requirement and on the "how to make" requirement separately. These are discussed separately below.

A. "How to use"

The Examiner stated that “[t]he scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the utility of the DNA encoding the extremely large number of polypeptides broadly encompassed by the claim.” (Office Action, page 6.)

Applicants submit that the scope of the claim is fully enabled by the specification. A polynucleotide encoding a polypeptide comprising "a naturally occurring amino acid sequence having at least 95% sequence identity to an amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2" encompasses polynucleotide variants encoding naturally occurring orthologs in related species, particularly human polypeptide variants with mutations that result in altered activity. These human polypeptide variants may result from single nucleotide polymorphisms (SNPs) in the polynucleotide. The polypeptide fragments of Claim 19 have kinase activity.

For all these reasons, the Specification fully enables the use of the claimed polynucleotides.

B. “How to make”

Applicants submit that all polynucleotides of Claim 19 as originally written are enabled by the specification. However, in order to expedite prosecution, Claim 19 has been amended. The polypeptide sequence of SEQ ID NO:2 is provided in the Sequence Listing. A polynucleotide sequence encoding the polypeptide sequence of SEQ ID NO:2 can be determined easily by one of skill in the art using the standard genetic code. “Naturally occurring” variants occur in nature; they are not created exclusively in a laboratory. The specification describes (e.g., page 19, line 16 through page 20, line 27) how to find naturally occurring analogs and homologs in other individuals and species and how to use BLAST to determine whether a given naturally occurring polynucleotide sequence encodes a polypeptides “having at least 95% sequence identity to the sequence of SEQ ID NO:2” scope.

Fragments having kinase activity are enabled in the specification. Kinase activity is described in the Specification e.g., on page 26, line 17 through page 27, line 18. Kinase activity assays are also well-known in the art. Claim 19 no longer recites immunogenic fragments.

Therefore, Claims 19, 20, and 22 satisfy the “how to make” requirement of 35 U.S.C. §

112, first paragraph.

For all these reasons, Applicants respectfully request the Examiner to withdraw the rejection of Claims 19, 20, and 22 under 35 U.S.C. § 112, first paragraph on this basis.

6. Rejection of Claims 19, 20, and 22 Under 35 U.S.C. § 112 first paragraph, written description

The Examiner rejected Claims 19, 20, and 22 under U.S.C. § 112 first paragraph, “as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” (Office Action, page 8.)

The Examiner discussed separately polynucleotides encoding fragments and variants of the polypeptide of SEQ ID NO:2. These will be discussed separately below.

A. Fragments

In particular the Examiner stated that:

Claim 19 (c) and (d) is specifically directed to those DNAs encoding a polypeptide comprising a biologically active or immunogenic fragments of SEQ ID NO:2. The specification, however, only provides a single representative species encompassed by this claim, that is the DNA of SEQ ID NO:2. There is no disclosure of any particular structure to function /activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties other than the biologically active or immunogenic, for which no predictability of structure is apparent. Since the claimed genus encompasses DNAs yet to be discovered, DNA constructs that encode fusion proteins, etc., the disclosed structural feature of SEQ ID NO:2 does not “constitute a substantial portion” of the claimed genus. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently described the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. (Office Action, pages 8 and 9.)

Applicants note that the Examiner, in this quoted passage from the rejection, referred to “the DNA of SEQ ID NO:2.” As shown in the Sequence Listing, SEQ ID NO:2 is a polypeptide

sequence while SEQ ID NO:1 is a polynucleotide sequence. Applicants assume that the Examiner inadvertently wrote "the DNA of SEQ ID NO:2," intending rather to write "the DNA of SEQ ID NO:1" and have directed their response to the rejection accordingly. If the Examiner intended otherwise, Applicants respectfully request the opportunity to address the rejection in a second, non-Final Office Action.

Although Applicants submit that the Specification fully supports Claim 19 as originally written, in the interest of expediting prosecution, Claim 19, subparagraph c, has been amended to recite "a fragment of the amino acid sequence of SEQ ID NO:2, wherein said fragment has kinase activity." Fragments having kinase activity are described in the specification (e.g., at page 7, lines 5-7 and page 26, line 17 through page 27, line 18). Kinase activity assays are also well-known in the art. Claim 19 as amended no longer recites "immunogenic fragments" and therefore the rejection as it pertains to immunogenic fragments is moot. Therefore, the claimed fragments are fully described in the Specification.

B. "Naturally occurring sequence"

The Examiner also rejected Claim 19 for reciting a polynucleotide sequence encoding a polypeptide comprising a "naturally-occurring sequence having at least 90% identity to the sequence of SEQ ID NO:2", grounding this basis for the rejection on the definition of "allelic sequence" in the specification.

Applicants have amended Claim 19, subparagraph b, to recite a polynucleotide sequence encoding a polypeptide comprising "a naturally occurring amino acid sequence having at least 95% sequence identity to an amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2." The specification describes where to find the claimed variants (see e.g., page 13, line 26, through page 14, line 12), gives the scope of the claims, and tells how one can determine whether a given polypeptide sequence falls within the scope of the claims. "Naturally occurring" polypeptide variants occur in nature; they are not created exclusively in a laboratory. The scope of the claim is described by the phrase having at least 95% sequence identity to an amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2." The specification describes how to use BLAST to determine whether a given sequence falls within the "at least 95% polypeptide sequence identity" scope (e.g., page 19, line 16 through page 20, line 27). Therefore,

the distinguishing attributes of the naturally occurring polypeptides having at least 95% sequence identity to the sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2 are fully described.

For all these reasons, Applicants respectfully request that the Examiner withdraw the rejection of Claims 19, 20, and 22 under 35 U.S.C. § 112, first paragraph, on this basis.

7. Rejections of Claim 19 Under 35 U.S.C. § 102(b) As Being Anticipated by Silvennoinen and by Wilks

The Examiner rejected Claim 19 under 35 U.S.C. § 102(b) as being anticipated by Silvennoinen and by Wilks.

The Examiner stated that Silvennoinen teaches a polypeptide sequence whose "best local similarity is 93.3% with that of SEQ ID NO:2" and that "the polynucleotide taught by Silvennoinen et al. encodes a polynucleotide [*sic*: polypeptide] comprising a naturally occurring amino acid sequence, as well a biologically active and immunogenic fragments of an amino acid sequence of SEQ ID NO:2." (Office Action, pages 10 and 11.)

The Examiner further stated that:

Wilks et al. teach two novel protein-tyrosine kinases, each with a second phosphotransferase-related catalytic domain, defining a new class of protein kinases. They specifically teach the cloning of a cDNA clone for murine Jak1 and Jak2 protein-tyrosine kinase. A comparison of the amino acid sequence of the murine Jak2 protein shows that its best local similarity is 95.3% with that of SEQ ID NO:2 between amino acid residue 536 and 1121. Further, the polynucleotide taught by Wilks et al. encodes a polynucleotide comprising a naturally occurring sequence, as well [*sic*: as] a biologically active and immunogenic fragments of an amino acid sequence of SEQ ID NO:2. These clones were isolated from cDNA libraries and sequenced using common DNA sequencing strategies. Therefore, claim 19 is anticipated by Silvennoinen [*sic*: Wilks] et al. (Office Action, page 11.)

Applicants note that Wilks does not disclose **any** polynucleotide sequence encoding murine Jak2 protein. Only the Jak2 polypeptide sequence is taught by Wilks. For this reason alone, Wilks is not a basis for a proper rejection under 35 U.S.C. § 102(b).

Neither Silvennoinen nor Wilks teach the polypeptide of SEQ ID NO:2; the

polynucleotide encoding the polypeptide of SEQ ID NO:2; a naturally occurring amino acid sequence having at least 95% sequence identity to an amino acid sequence of SEQ ID NO:2 over the entire length of SEQ ID NO:2; a polynucleotide encoding said naturally occurring amino acid sequence; a fragment of an amino acid sequence of SEQ ID NO:2, wherein said fragment has kinase activity; or a polynucleotide encoding said fragment. Amended Claim 19 no longer recites immunogenic fragments, and therefore, the rejection is moot as to immunogenic fragments.

Therefore, for all these reasons, neither Silvennoinen nor Wilks anticipates Claim 19. The Examiner is respectfully requested to withdraw the rejection of Claim 19 under 35 U.S.C. § 102(b) as being anticipated by Silvennoinen and by Wilks.

8. Rejections of Claims 20 and 22 Under 35 U.S.C. § 103(a) As Being Unpatentable Over Silvennoinen and Over Wilks

The Examiner rejected Claims 20 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Silvennoinen and over Wilks. Claims 20 and 22 depend from Claim 19. As discussed above in Section 7 above, neither Silvennoinen nor Wilks teach or suggest the polynucleotides of Claim 19.

Claims 20 and 22 depend from Claim 19. As noted above in Section 7, Claim 19 has been amended. With respect to the 35 U.S.C. § 103(a) rejection, Applicants respectfully submit that applying routine methods to the sequences disclosed in Silvennoinen or Wilks would not lead to the specific polynucleotides recited in Claim 19. (See *In re Deuel* (CA FC, 1995) 34 USPQ2d 1210.) Thus, Claim 19 would not have been obvious to one skilled in the art at the time the claimed invention was made, and Claim 19 and dependent Claims 20 and 22 are patentable over Silvennoinen and over Wilks. Therefore, Applicants respectfully request that the Examiner withdraw the rejection of Claims 20 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Silvennoinen and over Wilks.

9. Rejection of Claims 6 and 7 Under 35 U.S.C. § 103(a) As Being Unpatentable Over Silvennoinen

The Examiner rejected Claims 6 and 7 under U.S.C. § 103(a) as being unpatentable over

Silvennoinen, stating that:

One of ordinary skill in the art at the time of filing would have been motivated to use the sequence taught by Silvennoinen et al. to design oligomers for use as primers to amplify and determine the level of mRNA encoding the murine Jak2 protein or to isolate other mRNAs encoding related proteins such as human Jak2 using hybridization or polymerase chain reaction methodology. (Office Action, page 14.)

Applicants have canceled Claims 6 and 7, and therefore the rejection is moot. Applicants respectfully request that the Examiner withdraw the rejection of Claims 6 and 7 under U.S.C. § 103(a) as being unpatentable over Silvennoinen.

10. Rejection of Claims 19, 20, and 22 Under the Judicially Created Doctrine of Double Patenting over Claims 1-3 of U.S. Patent No. 5,914,393

The Examiner rejected Claims 19, 20, and 22 under the judicially created doctrine of double patenting over Claims 1-3 of U.S. Patent 5,914,393. The Examiner stated that:

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A purified polynucleotide consisting of a nucleic acid sequence encoding the polypeptide of SEQ ID NO:2.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent." (Office Action, Item 23, page 15.)

Applicants submit that there is no proper double patenting rejection for Claims 19, 20, and 22 over Claims 1-3 of U.S. Patent 5,914,393 under 35 U.S.C. § 121 which states in part that:

A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application.

Claims corresponding in scope to the present Claims 19, 20, and 22 (Claims 8, 9, and 10 of Application No. 08/567,508, which later issued as U.S. Patent 5,914,393) were restricted out during the prosecution of the application that became U.S. Patent 5,914,393. A Courtesy Copy of the Restriction Requirement mailed April 8, 1997 in U.S. Patent 5,914,393 (Paper No. 15) is

attached (Reference No. 1).

Claims 8, 9, and 10 as originally filed in the application that became U.S. Patent 5,914,393 were as follows (See Specification, page 44):

8. An expression vector comprising the polynucleotide of Claim 1.
9. A host cell transformed with the expression vector of Claim 8.
10. A method for producing a polypeptide, said method comprising the steps of:
 - a) culturing the host cell of Claim 9 under conditions suitable for the expression of the polypeptide; and
 - b) recovering the polypeptide from the host cell culture.

As shown in the copy of the Restriction Requirement, the Examiner in U.S. Patent 5,914,393 restricted the claims to groups including: Group I (Claims 1-5); Group II (Claims 1-3, 6, and 7); and Group III (Claims 1-3 and 8-10). The Examiner stated that:

Claims 1-3, drawn to sense and antisense polynucleotide sequences encoding human Jak2 kinase, are linking claims which are properly included in each of the three different Groups I-III where the invention includes a composition comprising such a polynucleotide, or a method utilizing such a polynucleotide. . .
.. Claims 1-3 and 11 will be examined only to the extent that they read on the elected group. See M.P.E.P. § 809.03 regarding linking claims. (Restriction Requirement, page 3.)

Applicants of U.S. Patent 5,914,393 elected Group II (Claims 1-3, 6, and 7), and amended Claims 1-3 were ultimately allowed. Contrary to USPTO practice as defined by the MPEP § 809.03, when linking claims 1-3 were allowed, the restriction requirement between Groups I, II, and III was not withdrawn. (See Courtesy Copy of the Notice of Allowance for U.S. Patent 5,914,393, Reference No. 2.) The restriction requirement was maintained between elected Group II and non-elected Group III in U.S. Patent 5,914,393, and therefore 35 U.S.C. § 121 prohibits a rejection of Claims 19, 20, and 22 over U.S. Patent 5,914,393 under the judicially created doctrine of double patenting. Applicants respectfully request that the Examiner withdraw the rejection of Claims 19, 20, and 22 over U.S. Patent 5,914,393 under the judicially created doctrine of double patenting.

11. Rejection of Claims 4, 6, 7, and 23-28 Under the Judicially Created Doctrine of Obviousness-Type Double Patenting over Claims 1-3 of U.S. Patent No. 5,914,393

The Examiner rejected Claims 4, 6, 7, and 23-28 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-3 of U.S. Patent No. 5,914,393. The Examiner stated that:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims drawn to a [*sic*: an] oligomer and its method of use (claims 6 and 7) or a composition comprising the antisense molecule (claim 4) of a polynucleotide comprising SEQ ID NO:1, as well as a method of detecting a polynucleotide comprising a sequence of SEQ ID NO:1 or variants thereof (claims 23-28) is [*sic*: are] obvious over claims to the polynucleotide consisting of SEQ ID NO:1 or the complement thereof (claims 1-3). (Office Action, page 16, Item 24.)

Applicants submit that this is not a proper rejection under the judicially created doctrine of obviousness-type double patenting. The MPEP (7th Edition, February 2000 Revision, § 804) states that:

Any obvious-type double patenting rejection should make clear:

- (A) The differences between the inventions defined by the conflicting claims—a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim is an obvious variation of the invention defined in a claim in the patent.

and states that the Examiner must "provide appropriate rationale of obviousness for any claims being rejected over the claims of the cited patent."

The Examiner's bare assertion of obviousness neither "provide[s] appropriate rationale of obviousness" nor follows the requirements listed above. Because the rejection of Claims 4, 6, 7, and 23-28 under the judicially created doctrine of obviousness-type double patenting is not proper and because the rejection as it pertains to canceled Claims 4, 6, and 7 is moot, Applicants respectfully request that the Examiner withdraw the rejection.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present

application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Agent at (650) 845-4646.

Respectfully submitted,
INCYTE GENOMICS, INC.

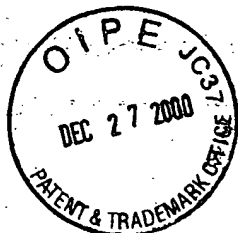
Date: December 21, 2000

Susan K. Sather
Susan K. Sather
Reg. No. 44,316
Direct Dial Telephone: (650) 845-4646

3160 Porter Drive
Palo Alto, California 94304
Phone: (650) 855-0555
Fax: (650) 849-8886



Vmk
4-19



APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/567,508	12/05/95	COLEMAN	R PF-004908
EXAMINER			

18N2/0408

LUCY J. BILLINGS, ESQ.
INCYTE PHARMACEUTICALS INC
3174 PORTER DRIVE
PALO ALTO CA 94304

Incyte Pharmaceuticals, Inc.
Patent Department
Received

ROSTERED	PAPER NUMBER
ART UNIT	

1819

15

APR 14 1997

DATE MAILED: 04/08/97

DATE 4-8-97

OFFICE ACTION Restriction

DUE 5-8-97

EXTS (4)

9-8-97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 0 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-18 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Claims 1-18 are now in the application.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5, drawn to sense and antisense nucleotide sequences of a polynucleotide encoding human Jak2 kinase, a pharmaceutical composition comprising such an antisense molecule, and a therapeutic method for using the latter, classified in Class 514, subclass 44, for example.

II. Claims 1-3, 6, and 7, drawn to sense and antisense nucleotide sequences of a polynucleotide encoding human Jak2 kinase, a diagnostic composition comprising an oligomer of such a molecule, and a diagnostic method utilizing the latter, classified in Class 435, subclass 6, for example.

III. Claims 1-3 and 8-10, drawn to sense and antisense nucleotide sequences of a polynucleotide encoding human Jak2 kinase, an expression vector comprising such a molecule, a cell transformed with such a vector, and a method for making a human Jak2 kinase utilizing the latter, classified in Class 435, subclass 69.1, for example.

IV. Claims 11 and 12, drawn to a purified human Jak2 kinase polypeptide, and a diagnostic composition comprising same, classified in Class 435, subclass 194, for example.

V. Claims 11, 13, and 14, drawn to a purified human Jak2 kinase polypeptide, a pharmaceutical composition comprising such a polypeptide, and a therapeutic method for using the latter, classified in Class 514, subclass 2, for example.

VI. Claims 15-17, drawn to an antibody specific for a human Jak2 kinase polypeptide, a diagnostic composition comprising such an antibody, and a diagnostic method utilizing the latter, classified in Class 530, subclass 387.2, for example.

VII. Claims 11 and 18, drawn to a purified human Jak2 kinase, and a method for detecting whether a compound binds to said polypeptide, classified in Class 435, subclass 7.1, for example.

Claims 1-3, drawn to sense and antisense polynucleotide sequences encoding human Jak2 kinase, are linking claims which are properly included in each of the three different Groups I-III where the invention includes a composition comprising such a polynucleotide, or a method utilizing such a polynucleotide. Claim 11, drawn to a purified human Jak2 kinase polypeptide, is a linking claim which is properly included in each of the three different Groups IV, V, and VII, where the invention includes a composition comprising such a polypeptide, or a method utilizing said polypeptide. Claims 1-3 and 11 will be examined only to the extent that they read on the elected group. See M.P.E.P. § 809.03 regarding linking claims.

The inventions are distinct, each from the other, because of the following reasons:

The sense and antisense polynucleotides of Invention I-III, the purified polypeptide of Inventions IV, V, and VII, and the antibody of Invention VII, are products which are materially different and patentably distinct from each other. The methods for making or using each of said polynucleotide, polypeptide, and antibody products require materials, technologies, and search of a body of prior art, that are distinctly different from those required to make or use each of the others.

The therapeutic antisense method of Invention I, the diagnostic oligonucleotide method of Claim II, the method for producing protein of Invention III, the protein diagnostic method of Invention IV, the protein therapeutic method of Invention V, the diagnostic antibody method of Invention VI, and the compound screening assay of Invention VII, are methods which are materially different and patentably distinct from each other, as each of these methods requires materials and method steps, technologies and search of a body of prior art, that are distinctly different from those required for each of the others.

Because these inventions are distinct for the reasons given

above and have acquired a separate status in the art due to their divergent subject matter and as shown by their separate classification, and because the search required for each of the Groups I-VII is not required for the each of the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

General Information Regarding Further Correspondence


Any inquiry concerning this or earlier communications from the examiner should be directed to Dr. Charles Rories, Group 1800, Art Unit 1819, at telephone number (703)-308-1120. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached at (703)-308-2035.

Papers related to this application may be submitted to Art Unit 1819 in Crystal Mall I by facsimile transmission to telephone number (703)-308-0294. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application, should be directed to the Group 1800 receptionist, at telephone number (703)-308-0196.

7 April 1997


Charles C. P. Rories
Patent Examiner
Art Unit 1819



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM21/0211

LUCY J. BILLINGS, ESQ.
INCYTE PHARMACEUTICALS INC
3174 PORTER DRIVE
PALO ALTO CA 94304

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/567,508	12/05/95	003	BISSON, B	1634 02/11/98
First Named Applicant	COLEMAN, ROGER			

TITLE OF INVENTION NOVEL HUMAN JAK2 KINASE

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 PF-0049US	536-023,500	A38	UTILITY	YES	\$660.00	05/11/98

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

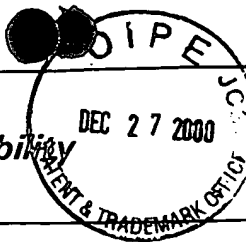
II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

YOUR COPY

Notice of Allowability



Application No.

08/567,508

Applicant(s)

Roger Coleman et al.

Examiner

Bradley L. Sisson

Group Art Unit

1807



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to the amendment received 15 December 1997.

☒ The allowed claim(s) is/are 1-3.

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 17.

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☐ Examiner's Statement of Reasons for Allowance

BRADLEY L. SISSON
PRIMARY EXAMINER
ART UNIT 1807

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☒ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☒ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.